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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,813	07/10/2003	Mitchell S. Wortzman	01-40076-USD3	2264

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Reed Smith LLP
2500 One Liberty Place
1650 Market Street
Philadelphia, PA 19103-7301

EXAMINER	
HOWARD, SHARON LEE	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/616,813	WORTZMAN ET AL.	
	Examiner	Art Unit	
	Sharon L. Howard	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *77-106* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *77-106* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The examiner acknowledges receipt of the preliminary amendment filed on 7/10/03.

Claims 1-76 have been cancelled.

Claim 78 has been amended.

Claims 77-106 are pending.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 77-106 rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon et al. (U.S. Patent No. 5,932,612) in view of .

Gordon teaches a method of using a skin lightening composition and for treating hyperpigmentation (see abstract). Gordon teaches about 0.05 to about 10% of ascorbic acid derivatives (see claim 22), such as magnesium ascorbityl phosphate and ascorbityl palmitate which can be used in the composition (see col.1, lines 64-67), as well as 1.5

to 4.0% of hydroquinone and other skin lightening agents (see col.2, lines 66-67, bridging col.3, lines 1 and 2). See Table 1 at col.2 for the teaching of 1.50 % w/w of ascorbyl palmitate, 0.15 % w/w/ of sodium bisulfite and other ingredients known in the art, prepared in a liquid, a gel or a cream formulation. Gordon teaches that according to the severity of the hyperpigmentation and the sensitivity of the affected skin area, the amount of the composition that is to be applied to the skin will vary, that is to say, usually from about 0.25 g to about 0.50 g of the cream which is described at col.2, lines 51-65 and see col.3, lines 3-10.

With respect to the silent teaching of the composition having a specific pH of about 5.5 to about 8.0, the pH is an inherent characteristic and is encompassed therein. The Gordon reference discloses the same composition, having properties to be desired such as reduced skin irritation and treating hyperpigmenation, while providing skin lightening which is known to be at least as effective as the conventional over-the-counter preparations (see abstract).

Gordon does not specifically teach adding an protected retinoid.

However, Clum et al. teaches stable skin care compositions comprising a water-in-oil emulsion base containing retinoids (see abstract) and methods for making the said compositions (see col.1, lines 12-17). Clum also teaches a water-soluble antioxidant such as ascorbic acid, sodium sulfite, sodium metabisulfite, sodium bisulfite, as well as any other known water-soluble antioxidant suitable with the other components of the compositions (see col.6, lines 1-9). Clum teaches ascorbyl palmitate, hydroquinone and mixtures thereof as well as any other known oil-soluble antioxidant suitable with the

other components of the compositions (see col.6, lines 10-17). Clum teaches that the antioxidants should be used in a stabilizing effective amount and may range in total preferably from about 0.01 to 1.0% and that the amount of antioxidants utilized in the compositions depends in part on the specific antioxidants selected, the amount of and specific retinoid being protected and the processing conditions (see col.6, lines 18-25). The pH of the compositions ranges preferably from about 4 to about 7 (see col.6, lines 53-55). .

Both references teach skin compositions containing ascorbic acid or ascorbic acid derivatives, hydroquinone, including a water-soluble antioxidant. It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. The idea of combining them flows logically from their having been individually taught in the prior art. *See In Kerkhove, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).*

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of the Gordon and the Clum references. One having ordinary skill in the art would have been motivated to modify the composition of Gordon to include a protected retinoid, because the third composition can be used for the same purpose of treating the skin or improving the quality of the skin.

Thus, the expected result would be to obtain a composition containing ascorbic acid or derivative(s) thereof, hydroquinone and an protected retinoid, known to be useful

for improving the quality of the skin and possessing properties such as good physical and chemical stability to be desired.

Double Patenting

Claims 77-106 of this application conflict with claims 54-76 of Application No.10/616,778. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

Claims 77-106 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 54-76 of copending Application No. 10/616,778. Although the conflicting claims are not identical, they are not patentably distinct from each other because Application No. 10/616,813 is species, Applicant is claiming adding an protected retinoid to the claimed method as claimed in generic claim 77 of Application No. '778.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Howard whose telephone number is (571) 272-0596. The examiner can normally be reached on 9:00am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharon Howard
July 7, 2004

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600